

Exhibit M

04/15/08 Notes

- **Pre cadaver surgery**
 - Is the only pathway for this procedure the same as the current TVT-O product or are there any variation of this pathway that are also acceptable?
 - What is the significance of the 12 cm mesh?
 - The 12cm tape is important because it will transverse through the obturator membrane.
 - Another important point to the mesh is that because we know the length of mesh on each side we know where the mesh will be placed, and know the structures that the mesh will be in.
 - Dr. DeLeval argues that the distance to the obturator membrane is 4.2cm, Dan believes it is approximately 5.5 based on measurements that were made during the development of TVT-Secur
 - Dr. DeLeval indicates that the distance to the obturator nerve is 6.8cm, Dan feels it is around 9cm.
- **Mini TVT-O Surgery on Cadaver**
 - This procedure was conducted with the same procedure as the current TVT-O
 - Note that the distance with the mesh folded in half is 6cm/side and the loops created by the suture is 4.5cm/side from the tip of the loop to the halfway point in the mesh.
 - Initial measurement of the scissors that have been inserted in the dissection and is believed to be at the obturator membrane is 2.5-3cm. Note they were feeling the location of the tip of the scissors is touching but not penetrating the membrane. Dan feels that they are at the internus muscle.
 - Dr. DeLeval says that he does not dissect through the obturator membrane because he feels that there should only be one pass through the membrane with minimal dissection. He feels by doing this he will reduce the incidence, and severity of pain in the procedure. His theory is that because there are so many nerve bundles in this area it is possible that the scissor dissection could hit a nerve branch and cause the pain that is reported with the current TVT-O procedure.
 - Dr. DeLeval passes the tape making a point that he is feeling his way along the pubic bone. He stresses that it is extremely important to have the passer against the bone and have a good tactile response.
 - Once the mesh has been passed and the loop has been created it was measured to be 5mm on either side, and he was using the Babcock.
 - Another observation that was made was that the sheath was curled at the exit points, and Dan pointed this out because a statement was made earlier that the sheaths would lay flat. This does not seem to be the case.

- The sheath was then removed, and it was noted that the removal of the sheath pulls on the mesh and tensions it upward slightly during the removal.
- When tensioning the tape it was noted that the mesh could move side to side fairly easily.
- In normal surgery would you pull on the suture to tighten the mesh?
 - Answer: Yes, would pull on the sutures similar to pulling on the mesh in a TVT-O procedure
- Reasons for the Babcock
 - Keep mesh flat
 - Prevent the mesh from pulling too tight when the sheaths are removed
- How would you compare the TVT-O placement to the Mini TVT-O procedure?
 - The tension on the mini should appear the same as the TVT-O tape once its placed.
- Dan questions how they know that the tape has been placed tight enough
 - Response: We do not know how tight mesh needs to be tightened initially but as long as they have control they can make subtle adjustments until they have found the right tension for a given patient.
- **Anatomical Dissection**
 - How thick is the externus muscle?
 - Approx. 2cm
 - As the mesh is dissected it was determined that the mesh was buried 1cm from the exterior of externus muscle.
 - Continued dissection showed that only 0.5cm of mesh had made it into the externus muscle
 - Distance of mesh to inferior pubic ramus was 2.5cm on the plane of the membrane
 - Distance of the tape in its intramuscular trajectory through the obturator membrane is 3 cm
 - It was determined that 7cm of mesh was implanted on the dissected side(left side if facing the patient)
 - It was noted that it is important to have tactile feel during the dissection so you know you are staying close to the bone
 - Dan also noted that the guide allows you to feel the bone when it is inserted, and as the introducer is passed you can feel the guide move away from the bone.
 - Important to procedure
 - Stay against bone
 - Tight rotation
 - Pullout value of the 5cm of mesh on the opposite side(not dissected)
 - 0.88 slip and 1.82 peak
 - Inserted the mesh with the blue tips, and pullout
 - .92 slip/peak(blue tip broke)

- Note mesh was 13cm tip to tip, and w/o sheath it required more force to insert
- **Discussion in Dr. De Leval's office**
 - Important factors of the procedure
 - Guide is integral for placement close to the bone and provides a protective feature
 - Need to have placement close to the bone
 - Why is placement close to the bone important?
 - You stay away from nerves
 - Improved efficacy
 - Safety
 - Importance of the guide
 - Controls the angle and pivot point of the inserter
 - Not using the guide could raise safety and efficacy questions
 - Education will probably not be an issue if the guide is not used
 - Note need to recognize that we need to assume we will need a guide for beginners that convert to this product for safety and efficacy.
 - Based on the measurements taken today the distance from the vaginal incision to the obturator membrane was approx. 5.5cm
 - Dan suggests that we should have mesh go through as much of the externus, obturator membrane, and internus for good fixation.
 - **More mesh = better fixation**
 - Dr. De Leval feels that we need to be able to follow the evolution of the procedure
 - Less dissection for the mini tape
 - Do not penetrate the obturator membrane
 - Note less dissection could raise some safety and efficacy questions
 - **It is possible that there could be a need a longer sling for an older woman and a shorter sling for a younger woman. His reasons for this are driven by the condition of tissue that is found in each type of patient varies.**
 - Current study with the mini tape does not have the perforation of the obturator membrane during the dissection.
 - Do we feel that we have to pull the mesh or can we push it from behind?
 - Note did not record an answer
 - Pulling up on sheath does tighten mesh
 - **There is no long term data and causes of erosions with laser cut mesh in their patients**
 - What is their opinion of the laser cut mesh?
 - It is possible that the laser cut could lead to erosions
 - Possible solution could be to go back to mechanically cut mesh to reduce the likelihood of erosions
 - Mechanically cut mesh could possibly also reduce insertion force of the mesh
 - **Erosions and Laser Cut Mesh**

- No problems with TVT-O laser cut mesh in either the 17 or 12 cm lengths
 - There have been erosions with 4-8 cm laser cut mesh
 - Is length the answer?
 - Length is not necessarily the answer, but erosion may be linked to the abrasive insertion of a laser cut mesh without a sheath.
 - What benefit does the sheath provide to prevent erosions?
 - TVT-O/Classic with sheath are very easy to insert
 - TVT- Secur with out sheath has an abrasive insertion.
 - Its possible that because of the less invasive mindset with Secur the docs may not open the incision enough and drag the mesh through a tissue which could also be a cause for erosions
- Take aways from conversation
 - Small tape not less than 12 cm
 - Tape has a sheath
 - Tension is adjustable
 - Stays fixed once placed
 - Has less immediate pain

04/16/08 Notes

- **Post Mini TVT Procedure Discussion**
 - What is Mini TVT-O Objective?
 - Maintain efficacy seen with TVT-O
 - Reduce immediate pain after procedure(immediate= 1day-1week)
 - Mindset is that if you reduce pain initially that will result in a reduction of incidents of persistent pain
 - Mini TVT-O Vs TVT-O
 - TVT-O you perforate the internus and obturator membrane during the dissection
 - Mini TVT-O you perforate the internus muscle and aim to avoid perforation into the membrane, however because the scissors are pointy a slight perforation may occur.
 - When dissecting during the TVT-O you cut and open the scissors during removal
 - Mini TVT-O is dissected up to the membrane, and the scissors are not opened when they are retracted.
 - Dr. De Leval simulates the closure of the vaginal incision for both TVT-O and Mini TVT-O
 - Is the loop in the Babcock during the Mini TVT-O larger than what has been used in the past with TVT-O?
 - Answer: No the loop is the same for both
 - What is the pain reducer in the Mini TVT-O technique?
 - Shorter Tape – not into the abductor muscle
 - Not perforating the obturator membrane with the scissors

- Reduction in the overall dissection
- To what degree is the immediate pain reduced with the Mini TVT-O procedure?
 - From 75% pain to 25% pain
- How soon can the patient resume normal activity?
 - Patients that have this Mini TVT-O procedure must stay in the hospital for 24 hrs post procedure
 - Patients are directed that they must not do any strenuous, or sexual activities for 3-4 weeks post op.
 - If patient has coughing fit within the 24hr period it is likely that their mesh will fail
 - Note: Keep catheter in until morning after surgery.
 - Note: Retention is low maybe 1%
- If patient cannot void then what?
 - Put catheter back in to empty bladder
 - If patient still cannot void then the tape must be taken down
- Identify 3 variables of less pain
 - Minimum dissection (no opening of scissors during retraction)
 - Small mesh not left in the abductor muscle
 - Avoid perforation of obturator membrane
- Have you done the minimum dissection for the TVT-O Classic procedures?
 - No, but this could be done to see the effect but to evaluate this arm would take about 6 months to get a sample group
- If we do not use the guide would we compromise safety?
 - Need the guide even without perforation of the membrane to ensure we do not enter the retropubic space
- Most important part of this study is to show efficacy with short mesh.
- Dan explains that its beyond just having efficacy with one surgeon, and we need to ensure efficacy with this device in other surgeons hands
- When it comes to tensioning there is no difference in the appearance of the mini mesh and the classic TVT-O procedure
- Indication from Dr. De Leval is that the only difference in tensioning is that with one you pull on the mesh and the other you are pulling on suture.
- Have you been simulating the closing of the vaginal incision on both TVT-O and Mini TVT-O
 - Yes he has been doing this for both procedures.

*Jason Hernandez additional notes from visit with Pr. de Leval & Dr. Waltregny***Cadaver Lab Apr 15**

- Prof de Leval feels learning curve with mini TVT-O is virtually none for existing TVT-O users as he believes it's essentially the same procedure technique
- Prof de Leval stated he does not tension differently between classic TVT-O and mini TVT-O
 - Dan presented his experience with TVT SECUR and felt mini-slings should be tensioned slightly tighter than traditional slings
 - Consensus appeared to be that mini-slings should be tensioned "snug" against the urethra
- Anatomical pathway for TVT-O and mini TVT-O is important versus other alternative obturator pathways that could be used because it avoids damage to the dorsal nerve of the clitoris
- Dave Robinson inquired about potential to not trim the sutures at the level of the skin immediately post-op to facilitate possible post-op tensioning adjustment (Pr. de Leval and Dr. Waltregny had not considered or tried that approach)
 - Axel Arnaud commented he was aware of traditional tape meshes being left exiting the body for potential post-op tensioning adjustability, but that the tape was prone to inciting infection
 - Axel commented that the sutures may not cause the same undesired response
- Tape length was discussed based upon cadaveric dissection which showed the mini TVT-O Pr de Leval placed was not even bilaterally
 - Dr. Waltregny commented that he believes current mini-slings, specifically TVT SECUR and AMS MINIARC, are too short to achieve good fixation because they cannot reach the ideal anatomic structures
- It was noted during the cadaveric dissection after passage of mini TVT-O that the nylon sutures passed through the gracilis
- Dave Robinson noted that the procedural technique regarding scissor dissection and wing guide insertion used between classic TVT-O and mini TVT-O was different
 - Pr de Leval commented they aim to not perforate the obturator membrane or obturator internus muscle with scissors or wing guide when performing mini TVT-O and also do not spread the scissors upon removal from the dissected track
 - Dave Robinson inquired if this different technique could be contributing to the decreased incidence and severity of immediate post-op pain
 - All attendees agreed this was a possibility and could not be ruled out based upon the current clinical study design
- It was noted that one of the design device concepts Dan brought had mesh that was 1 cm longer than it was supposed to be (13 cm versus 12 cm)
- Several device design concepts were placed anatomically in the cadaver and pull out force measures were obtained for both slip and peak measurements
 - Dr. Waltregny debated value of these measurements for citing factors including applicability of cadaveric tissue to actual patients plus one tape

- had been transected at the mid-line prior to obtaining pull out force measurements; Dan noted this in the measurements obtained
- Dan presented the options he had prepared for various helical passer depths and obtained feedback from the surgeons
 - Dr. Waltregny specifically cited he felt the 2" may not provide enough room to work in the operative field with the handles remaining attached to the device
 - Dan evaluated spacing during passage of the devices cadaverically
 - Dan presented the options he had prepared for various tip designs including versions with anchors and pockets
 - Dr. Waltregny cited the concept with pockets looked "cheap" and not like a high quality device
 - Dr. Waltregny asked if the tips remain in the patient which Dan replied they do for several concepts including the one with polypropylene anchors
 - Dan presented and discussed options he had prepared for various designs with removable handles
 - Ideal tape length was discussed
 - Based on the cadaveric dissection done, it appeared that with a 12 cm mesh (using mini TVT-O for the example) the 6 cm of mesh on each side just reached the obturator externus
 - Due to potential for surgeons to not always achieve perfect bilateral placement, Dan recommended consideration be given to 14 cm mesh which would allow approximately 7 cm per side versus 6 cm which may help ensure fixation of the mesh into the obturator externus occurs
 - Dr. Waltregny asked Dan how much difference would current classic TVT-O users perceive between a 14 cm mesh and what he felt was an average of about 17 cm of mesh implant placed in the average patient with TVT-O
 - A consensus on mesh length was not achieved at this time, but during subsequent meetings the following day consensus was achieved that the longer the mesh the greater the confidence in achieving long-term efficacy (durability)
 - The specific perceived cause of thigh pain was discussed
 - Dr. Waltregny cited he did not know what specifically causes thigh pain experienced by some patients treated with classic TVT-O
 - Dr. Waltregny cited that with some patients they may experience thigh pain on one side or the other with great variance in presence or degree of pain between the two different sides
 - Dr. Waltregny stated the clinical follow-up they had (1 month at time of visit with 6 month follow-up expected in May 2008) showed patients treated with mini TVT-O had less pain than those treated with classic TVT-O, but that there was still some pain (mini TVT-O reduces, but does not eliminate immediate post-op pain)
 - Tensioning procedure steps and tactile feel was discussed between both classic TVT-O and mini TVT-O versus the exitless device design concepts shared

- Both Pr de Leval and Dr. Waltregny agreed that tensioning via either the sheath or sutures abdominally is completely different than tensioning using an inserter below; doctors using TVT and classic TVT-O are used to tensioning by pulling up on the sheath above the abdomen and we shouldn't underestimate the difference experienced by surgeons when having to tension via different technique
- Tactile feel was discussed by Pr de Leval who inserted one of the exitless device design concepts provided by Dan into the cadaver
 - The lack of a sheath caused much greater resistance during insertion than is experienced with either classic TVT-O or mini TVT-O
 - Dr. Waltregny cited this may require a larger dissection which is against one advantage he perceives of mini-slings which is the potential for even less dissection than traditional TVT-O or TVT
 - Dan cited that for an exitless sling having a sheath to facilitate more familiar tactile feel and avoid necessitating larger dissection was a possibility
 - Additionally Dan showed device design concepts with tapered edges which may reduce resistance and negate need for larger dissection
- Discussion of the need for a wing guide with a next generation TVT-O device was held
 - All who expressed a specific opinion on this issue felt having a wing guide as part of the next generation TVT-O device would be positive
- Mechanical versus Laser Cut Mesh (LCM) was discussed
 - It was noted that mini TVT-O uses LCM
 - Dan cited that some of the device design concepts used in the lab were made with mechanical cut mesh
- Dan asked Pr de Leval and Dr. Waltregny to comment on whether or not they had any concerns with leaving polypropylene anchors in the body to improve fixation
 - Dr. Waltregny commented that he did not have any concerns and felt pain would not be an issue given the size of the anchors required and placement within the anatomy; Pr de Leval agreed and added no additional comments
- It should be noted that the anchor of one of the device design concepts broke free from the mesh during a pull out force test and remained in the cadaver tissue
 - Upon observing this, Dr. Waltregny cited a balance needs to be made between holding force and being able to loosen the tape beyond just stretching for those cases where post-op retention occurs
- Dan was asked by Pr de Leval and Dr. Waltregny to pass one of the device design concepts in the cadaver with both handles in place (not removed after insertion of the first side) to evaluate if this could easily be done without interference from the non-operative handle in the operating field
 - Dan was able to successfully pass both sides of the tape with the handles in place with the device design concept without interference
- Dan presented an option ETHICON had generated for a novel approach to post-operative tensioning adjustment of the tape
 - All of the surgeons responded favorably to this concept and the overall potential ability to be able to fine tune tensioning post-op

Evening Discussion at CHU Apr 15 (after cadaver lab)

- All agreed again the wing guide is very important
- Importance of tape positioning in relation to the bone was discussed
 - All agreed tape placement should be in close proximity to the bone for the following reasons:
 - If not closer to the bone, then the tape is therefore closer to the nerve
 - Pr de Leval and Dr. Waltregny cited their belief that placement close to the bone is a contributing factor to achieving durable results
- Pr de Leval commented he was impressed that in the cadaver passage of mini TVT-O nearly 3 cm of tape was within the muscle
- It was agreed that with mini TVT-O having the same general anatomic pathway as classic TVT-O which is proven safe and effective was favorable
- Modified technique Pr de Leval and Dr. Waltregny use for the mini TVT-O procedure was discussed
 - Note: technique is that they aim to not perforate the obturator membrane or internus muscle and that during scissor dissection the scissors are not retracted from the tissue in a spread position which is the case with current technique for classic TVT-O
 - The ETHICON team raised the issue that training or technique might become more difficult using this modified technique because if the wing guide is not securely fixated a surgeon could enter into different tissue planes inadvertently upon passage of the helical passer than they would have using the standard technique for classic TVT-O
 - Dr. Waltregny cited we should consider modifying the IFU for classic TVT-O as an evolution of the procedure and that many surgeons today are more experienced in obturator sling procedures so they should not have much difficulty in safely performing the modified technique
 - Harel pointed out that we are not able to definitively make the assumption surgeon's who will choose to use classic TVT-O in the future are more skilled or experienced surgeons than those who began using the product upon launch
- Debate around location from mid-line of key anatomic structures was held with Pr de Leval citing he believes the obturator membrane is situated at approximately 5.5cm from the midsagittal vaginal incision
- Length of mesh again discussed
 - Consensus seemed to be reached that the length of mesh aids in fixation force and the ability to ensure penetration bilaterally of key anatomical structures to achieve long-term fixation (greater likelihood of durability)
- Discussion of role of the wing guide was held
 - Consensus is that role of the wing guide is a safety feature
 - Dan cited by securing the wing guide in at least two structures (ie. obturator membrane and obturator muscle) it ensures the helical passer follows the correct track for safe and effective placement of the tape

- Dan also cited many classic TVT-O users including preceptors are known to state anecdotally that once the wing guide has been correctly placed “the procedure is over” as the remaining steps have had undesirable variability removed
- Pr de Leval provided several comments listed below at this time in the conversation:
 - We should follow an evolution for the classic TVT-O procedure
 - Less dissection being used for the mini TVT-O may allow better holding force
 - We should acknowledge the increased experience of many surgeons with this (classic TVT-O) technique
 - Regarding the debate around sling length, it could be that a longer sling may benefit patients who are older or with intrinsic sphincter deficiency (ISD) than younger women who would be fine with a shorter sling due to having better tissue integrity
 - The seemingly slight variation of tensioning from below with inserters versus the visual and tactile feel surgeons are used to by tensioning from above the abdomen via the sheaths cannot be overlooked
- A discussion of the pros & cons of laser cut versus mechanical cut mesh was held
 - Consensus was that LCM has more rigid edges and stiffer feel than mechanical cut mesh
 - It was noted that no clinical study has specifically been done regarding LCM versus mechanical cut mesh although bench top testing has shown equivalence in the physiologic range
 - It was noted that some surgeons have reported lateral erosions with TVT SECUR which uses LCM
 - Pr de Leval and Dr. Waltregny cited the three potential benefits of using mechanical cut mesh in a next generation TVT-O mini-sling:
 - Tensioning would be more similar to current tensioning techniques for experienced TVT and classic TVT-O users
 - GYNECARE has a longer track record with mechanical cut mesh in TVT with a very low rate of reported erosions
 - The edges of mechanical cut mesh do not feel as stiff as LCM and this may facilitate easier insertion which is particularly important if the next generation TVT-O mini-sling does not have sheaths over the mesh during insertion
- The importance of sheaths in the current TVT procedures was discussed
 - It was cited that having sheaths over the tape during insertion may have the benefit of a smoother insertion for less pressure which meets surgeon preference, but also may be less prone to erosions as the smoother sheaths would not drag vaginal epithelium or tissue as it is passed through the body; tape alone without sheaths could have this dragging effect
 - The hypothesis proposed by Dr. Waltregny is that inserting mesh with no sheath pulls tissue versus passing with less disruption
- Tissue structures necessary to achieve both immediate and long-term (durability) fixation were discussed

- It was agreed that the tissue structures that provide greatest fixation are not empirically clear in any current or previous clinical literature
- Discussion of optimal tape length was again held
 - Pr de Leval and Dr. Waltregny cited that the early analysis of initial mini TVT-O clinical procedures reaching six month follow-up shows efficacy of mini TVT-O with 12 cm mesh as being similar or equal to classic TVT-O
 - Anatomically Dr. Waltregny cited that he believes anatomically there is adipose (fat) or loose connective tissue 3 cm lateral to the urethra and then 3 cm of muscle beyond the obturator membrane
- Pr de Leval and Dr. Waltregny stated they feel the biggest unmet need for surgeons currently using classic TVT-O is thigh pain which is not an issue with competing procedure retropubic TVT
- Pr de Leval and Dr. Waltregny cited a midline mark may be beneficial to help ensure bilateral placement in key targeted anatomical structures

Morning Discussion Apr 16 (after mini TVT-O procedures at CHU)

- Pr de Leval cited the goals of mini TVT-O as:
 - Same efficacy of classic TVT-O
 - Reduced incidence and severity of immediate post-op pain in the first week post-op
- Clinical data being generated by Pr de Leval and Dr. Waltregny for mini TVT-O assesses immediate post-op pain at day 0, 1, 30
 - One month follow-up showed a lower incidence and severity of immediate post-op pain at day 0, 1 & 30
- Dr. Waltregny cited that he believed previous clinical data on classic TVT-O which reported on post-op thigh pain with the highest percentage reported for this measure was a clinical study published in 2006 by the British Journal of Urology from Dr. Marcus Carey
 - Members of the ETHICON team thought they had either seen or heard anecdotally from surgeons that 3%-5% of patients had post-op thigh pain although this could not be immediately confirmed
- Pr de Leval and Dr. Waltregny cited they believe a factor contributing to the pain some patients experience post-op after classic TVT-O is because the mesh causes irritation in the abductor muscle
- Patient benefit of reduction in pain post-op beyond just less pain is reduced analgesic medication required
- The post-op protocol for both classic TVT-O and mini TVT-O was presented by Dr. Waltregny and Pr de Leval
 - Post-op protocol at CHU is 24-hour hospital stay prior to discharge and restricted activity for 3 to 4 weeks (restricted activity includes no sex, no heavy lifting and no activity that is physically exerting)
 - It was cited by members of the ETHICON team that this is not the protocol followed by many US surgeons who perform classic TVT-O and there was concern expressed about whether or not the same clinical

outcomes would occur under protocols that were less strict such as immediate post-op discharge and return to normal after 1 to 2 weeks

- It was discussed that with two potential variables that may have contributed to the pain reduction (incidence & severity) found with mini TVT-O versus classic TVT-O, we would not be able to conclusively attribute the reduction to the mini TVT-O device
 - Dave asked how long it may take for Pr de Leval and Dr. Waltregny to recruit for the study if it were done again with either additional arms to isolate the variables or using same technique for both devices
 - Dr. Waltregny responded to reach 40 patients per arm for another two arm study would take six months
- Dr. Waltregny cited that in addition to aiding the surgeon in avoiding the bladder, the wing guide also ensures the surgeon does not enter the pelvic space
- Final discussion regarding any potential tensioning differences being employed by Pr de Leval and Dr. Waltregny between classic TVT-O and mini TVT-O
 - Dan felt he may have observed slight differences between the two based on his previous experience having seen Pr de Leval perform classic TVT-O procedures
 - Pr de Leval cited he did not tension the two devices differently

Note: classic TVT-O nomenclature is used to differentiate the GYNECARE TVT* Obturator System Tension-free Support for Incontinence from the mini TVT-O procedure / device being used by Pr Jean de Leval and Dr. David Waltregny

Note: some conversations with Pr de Leval required translation from French to English; translation was provided by Dr. Waltregny and Axel Arnaud as needed